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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,705	02/21/2002	John Barthelow Classen	22499-68466	1273

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EXAMINER	
LEROUX, ETIENNE PIERRE	

ART UNIT	PAPER NUMBER
2161	

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08/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,705	CLASSEN, JOHN BARTHELOW	
	Examiner	Art Unit	
	Etienne P LeRoux	2161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/15/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *250-300* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *250-300* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ___ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Status:

Claims 250–300 are pending: claims 1-249 have been cancelled. Claims 250-300 are rejected as detailed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 250, 256, 257, 270, 271, 272, 273, 274, 275, 276, 278, 281, 282, 285, 286, 287-290, 292 and 294-298 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant disclosed prior art (ADPA) in view of Pub No 2002/0039990 (Stanton), hereafter Stanton and further in view of Pat No 5,991,751 (Rivette et al), hereafter Rivette. and further in view of US Pat No 6,458,958 (D'Ambra et al), hereafter D'Ambra.

Claim 250, 256, 270, 271, 274, 275, 278, 280,. 287-290, 292, 293, 294 and 295-297:

ADPA discloses:

accessing one or more data sources [ADPA, paragraph 50]

wherein at least one data source comprises adverse event data [ADPA, Merck Manual, paragraph 50]

ADPA discloses the elements of the claimed invention as noted above but does not disclose analyzing and comparing adverse event data associated with a product of manufacture

or device, with at least one previously-known adverse event associated with the product or device. Stanton discloses analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device [Stanton: paragraph 19, drug will be effective/drug will not be effective, Stanton paragraph 114, adverse events associated with chemotherapy drugs]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify ADPA to include analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device as taught by Stanton for the purpose of determining possible adverse effects of a drug.

The combination of ADPA and Stanton discloses identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential adverse event, identifying at least one previously unreported method of use for the product or device, [Stanton: paragraph 53, treatment method]

The combination of ADPA and Stanton discloses creating a database of proprietary essential adverse event information the database storing data regarding the at least one novel essential adverse event [Stanton: paragraph 99]

The combination of ADPA and Stanton discloses the elements of the claimed invention as noted above but does not disclose wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or patent publication. Rivette discloses wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or

patent publication [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of above references to include wherein the database comprises at least one of a patent application, patent publication, or data contained in at least one patent, patent application or patent publication as taught by Rivette for the purpose of managing an inventor's database of intellectual property.

The combination of ADPA, Stanton and Rivette disclose documenting inventorship of the at least one method of use for the product or device [Rivette: abstract]

The combination of ADPA, Stanton and Rivette discloses the elements of the claimed invention as noted above but does not disclose wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warnings about the essential adverse event, providing instructions for avoiding an essential adverse event and any combination thereof. D'Ambra discloses wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warnings about the essential adverse event, providing instructions for avoiding an essential adverse event and any combination thereof [col 1, lines 60-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the above limitation(s) for the purpose of warning the public of life threatening side effects associated with the use of a product [col 1, lines 50-65].

Claims 257, 281 and 282:

The combination of ADPA, Stanton and Rivette disclose the elements of claim 250 as noted above but does not disclose sales data. Official Notice is taken that sales data is well-known and expected in the art. It would have been obvious to one of ordinary skill in the art at

the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information for the purpose of determining the value of commercializing a product.

Claims 272, 273 and 276:

The combination of ADPA, Stanton and Rivette disclose wherein the novel method of use is a restricted use in at least one population subgroup when there is observed to be high risk of at least one adverse event associated with exposure to or use of the product or device [Stanton, paragraph 90]

Claims 251, 252, 254, 258 and 279 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette and D'Ambra and further in view of US Pat No 5,678,234 issued to Colombo et al (hereafter Colombo), as best examine is able to ascertain.

Claims 251, 252, 254 and 279:

The combination of ADPA, Stanton, Rivette and D'Ambra discloses the elements of claim 250 as noted above but does not disclose determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event. Colombo discloses determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event [col 3, lines 60-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include determining value of commercializing the

at least one new characteristic or use determined from the at least one identified essential adverse event as taught by Colombo for the purpose of making a profit.

Claim 258:

Dimino'Ambra discloses a drug interaction [col 1, lines 50-65]

Claims 253 and 255 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo and further in view of US Pat No 6,018,714 issued to Risen et al (hereafter Risen), as best examiner is able to ascertain.

Claims 253 and 255:

The combination of ADPA, Stanton, Rivette, D'Ambra and Colombo discloses the elements of claims 250-252 as noted above but does not disclose the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information. Risen discloses the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information as taught by Risen for the purpose of deriving income from intellectual property.

Claims 259, 260, 261-269, 277, 283, 284 and 291 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton and Rivette and Risen.

Claims 259 and 277:

Regarding claim 259, Official Notice is taken that raw commercial or sales data is well-known and expected in the art.

Claim 260:

Regarding claim 260, Official Notice is taken that proprietary information is well-known and expected in the art.

Claims 261-263, 266 and 267:

Regarding claim 261, Official Notice is taken that a medical product is well-known and expected in the art.

Claims 264, 265, 268 and 269:

Regarding claim 264, Official Notice is taken that a non-medical product is well-known and expected in the art.

Claims 283 and 284:

Regarding claim 283, Official Notice is taken that product exposure times are well-known and expected in the art.

Claim 291:

Regarding claim 291, Official Notice is taken that date of inventorship is well-known and expected in the art.

Claims 299 and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of ADPA, Stanton and Rivette as applied to claim 250 above, and further in view of US Pat No 3,885,566 (Jacob), hereafter Jacob.

Claims 299 and 300:

The combination of ADPA, Stanton and Rivette disclose the essential elements of the claimed invention as noted above but does not disclose wherein the novel use further comprises providing novel printed product safety information in connection with product packaging. Jacob providing novel printed product safety information in connection with product packaging [col 1, lines 35-65]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include providing novel printed product safety information in connection with product packaging as taught by Jacob for the purpose of ensuring the safety of disposable diapers.

Response to Arguments

Applicant's arguments submitted 8/15/2007 have been considered but are not persuasive for the reasons given below.

Applicant Argues:

Applicant states in the fourth paragraph of page 11 "In claim 250, the examiner argues that neither the phrase novel essential adverse event nor novel method of use is described in the specification. Presumably it is the term novel that the examiner finds objectionable, although applicant cannot be certain of the examiner's basis for the rejection since no further explanation is given. The basis for essential adverse event was fully argued by applicant in the response to

the previous office action, so there can be no question about the meaning of the term. Support may be found at least at paragraphs [0011], [0040], [0042], [0048], [0051], [0056], [0070], [0072], [0076], [0077], 0079], [0085], [0087] and [0095-0098].

Examiner Responds:

Examiner is not persuaded. Applicant does not provide a specific and deliberate definition of essential adverse event but merely provides exemplary citations. The most definitive statement is included in paragraph 86 of the specification which states "The final determination of what is essential information is determined by a regulatory agency such as the FDA." Applicant provides no information regarding how such a determination is made by the FDA and therefore, "essential adverse event is not fully supported in the specification" such that a skilled artisan can make and use the invention.

Paragraph 51 of the specification states that a new essential adverse event can mean a newly discovered adverse reaction such as the discovery of an increased rate of seizures associated with a drug. For purposes of this examination, essential adverse event will be interpreted with respect to paragraph 51 to mean a newly discovered adverse reaction.

Paragraph 50 of the specification states that essential adverse events are included in the Pohysician's Desk Refernce, The Merck Manual, data from regulatory agencies such as the FDA, and published literature found on databases such as MEDLINE. Examiner is **confused** (emphasis added). The law prohibits patenting published material. Is difficult to understand how applicant is trying to patent material found in The Merck Manual, for example.

Applicant Argues:

Applicant states in the fourth paragraph of page 4 that applicant is willing to amend the definition of an adverse event in paragraph 95.

Examiner Responds:

Examiner is not persuaded. Examiner maintains such amendment of the specification constitutes new matter and will not be entered into the specification. Applicant should consider issuing a continuation-in-part.

Applicant Argues:

Applicant states that "new dosing regimen" is fully supported in the specification.

Examiner Responds:

Examiner is not persuaded. "New dosing regimen" is not included in paragraph 36 which is referenced by applicant.

Applicant Argues:

Applicant states in the first paragraph of page 15 "Accordingly, Applicant asks for a withdrawal by the examiner that suggests that Applicant has admitted to disclosing any prior art of any kind with regard to Applicant's claimed invention ."

Examiner Responds:

Examiner is not persuaded. Paragraph of the specification includes the following statement:

Sources of prior known essential adverse events can include package inserts, the Physician's Desk Reference, The Merck Manual, data from regulatory agencies such as the FDA, and published literature found on databases such as MEDLINE.

Examiner maintains that the law does not permit the patenting of prior published material. It does not matter what applicant calls such published material, prior art or something else.

Applicant Argues:

Applicant states in the second paragraph of page 15 "However, Stantaon was published April 4, 2002(almost 1 year after effective filing date (February 22, 2001) of Applicant's U.S. Provisional Application No. 60/270,697.

Examiner Responds:

Examiner is not persuaded. Examiner maintains that Stanton is prior art under 102 (e).

Applicant Argues:

Applicant states that Stanton is related to genetic screening.

Examiner Responds:

Examiner is not persuaded. The invention as claimed does not expressly exclude genetic screening and thus one of ordinary skill in the art faced with the problem of analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device would have been motivated to consider the disclosure of Stanton [Stanton: paragraph 19, drug will be effective/drug will not be effective, Stanton paragraph 114, adverse events associated with chemotherapy drugs]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify ADPA to include analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse

event associated with the product or device as taught by Stanton for the purpose of determining possible adverse effects of a drug.

Applicant Argues:

Applicant states in the second paragraph of page 17 the following:

Furthermore, if a clinical trial were needed to obtain regulatory agency approval, as is the case with Stanton's published application then the resulting data is not essential since a regulatory body does not require that the information be made public.

Examiner Responds:

Examiner is not persuaded. Above definition of essential data constitutes new matter and will not be entered into the record.

Applicant Argues:

Applicant argues on pages 18-21, limitations which are not claimed.

Examiner Responds:

Examiner is not persuaded.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne P. LeRoux whose telephone number is (571) 272-4022. The examiner can normally be reached Monday through Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Apu Mofiz can be reached on (571) 272-4080. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Etienne LeRoux

8/29/2007

Etienne P LeRoux

ETIENNE LEROUX
PRIMARY EXAMINER